

REMARKS

The Examiner is thanked for the due consideration given the application

Claims 12-17 are pending in the application. The claims have been amended to better set forth the claimed invention.

No new matter is believed to be added to the application by this amendment.

Entry of this amendment under 37 CFR §1.116 is respectfully requested as it places the application in condition for allowance or, alternately, places the application in better form for appeal.

Art Rejections

Claims 12-14 and 17 have been rejected under 35 USC §102(b) as being anticipated by BEITER (U.S. Patent 4,545,376). Claims 15 and 16 have been rejected under 35 USC §103(a) as being unpatentable over CROSSMAN (GB 2352403) in view of HIGGINS (U.S. Patent 3,358,689). These rejections are respectfully traversed.

The present invention pertains to the design of a twist off cap or tab on a lancet that is illustrated, by way of example, in Figure 1 of the application, which is reproduced below.

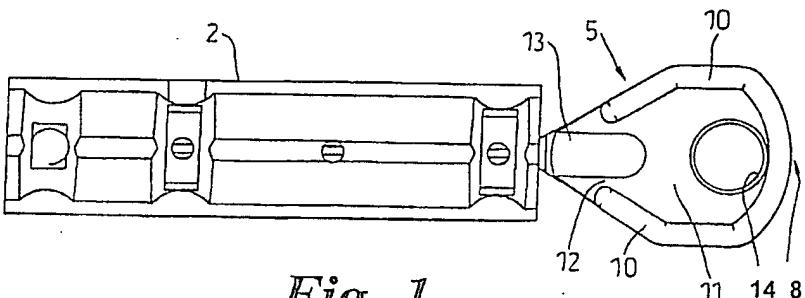


Fig. 1

In the present invention, the removable guard is described as being "located over the pointed tip of the needle". This phrase was intended to make it clear that the pointed tip is effectively shrouded by the removable guard. In fact the "further thickened region" of claim 12 encases the tip of the needle to keep it sterile, to prevent needle stick injuries, and to prevent mechanical damage to the needle tip. Instantly amended claim 12 emphasizes that the tip of the needle is encased by the further thickened region.

This feature was already explicit in method claim 15, but this claim has also been amended to also the features that the peripheral thickened hollow region is of C or U-shape and spaced from the further enlarged hollow region by a gap of thinner section.

As previously indicated in the application, the present invention addresses a problem that arises when

injection moulding a releasable cap around the needle tip of the lancet.

In order to reduce the pricking sensation in use, the lancet needle tip should be as fine as possible, but this means that, unprotected, it can be inadvertently bent before use quite easily and this can give problems to registration in an automatic finger pricking device and/or a diagnostic test strip, etc.

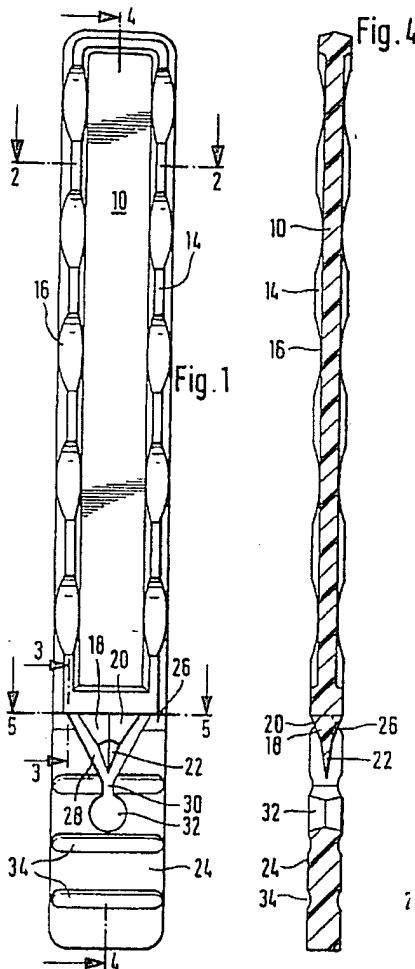
The applicants have found that, with the high pressures involved in injecting moulding, and the relatively viscous nature of the molten plastics material, the in-rush of molten plastics material into the mould during the injection moulding process can deflect the needle tip out of its longitudinal and alignment. Thus, in an arrangement such as in CROSSMAN the rush of plastic around the ring shaped section of the mould can disturb the alignment of the needle tip.

In the present invention the cross sections of the cap and the mould are therefore carefully selected to ensure that the flow of molten plastic is temporarily slowed or choked before it passes into the part of the mould cavity which surrounds the needle tip.

Thus, as set out in claim 15, the mould has an outer peripheral thickened hollow section of C- or U-shape which

is spaced by a thinner section from a further thickened region encasing the needle tip. The ends of the C- or U-shaped peripheral hollow region are spaced from the further thicker section encasing the needle tip by a gap which is bridged only by the thinner section. This means that the in-rush of molten plastics material into the outer peripheral region is slowed by the thinner bridging region before it reaches the further enlarged region, thus minimizing the possibility of damage to the needle.

Looking now specifically at BEITER, the Official Action refers to Figures 1 and 4 of the reference, which are reproduced below.



BEITER describes a lancet in which the needle tip is provided with a protective yoke intended to protect the tip. It is to be particularly noted that the yoke is spaced from the tip and is not in contact with it.

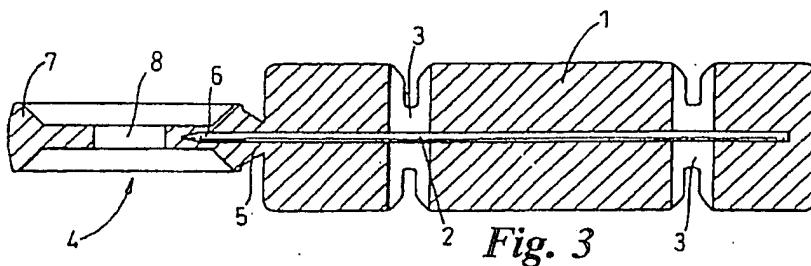
There is neither an equivalent to the further thickened region encasing the tip of the needle of claim 12 of the present invention, nor of the choking arrangement

whereby the flow of plastics material is choked before it enters a cavity around the needle tip to encase it in plastics material. Claims 12-14 and 17 are therefore patentably distinguished from BEITER.

BEITER thus fails to anticipate the present invention.

Regarding the unpatentability rejection of claims 15 and 16 under 35 USC §103(a), claim 15 now includes a feature that the mould has a peripheral thickened hollow region of C- or U-shape leading to a thinner hollow section approaching the needle tip and a further enlarged hollow region encasing the needle tip, with the further thickened region being spaced from the adjacent ends of the peripheral thickened region leaving a gap that is bridged only by a thinner section.

CROSSMAN fails to disclose such an arrangement. In CROSSMAN there is a substantially uninterrupted ring shaped cavity and there is no thinner section or choking action as required by the claim. Indeed, the arrangement of Crossman makes no attempt to restrain the flow of plastic from the entry point around the ring to the needle. See Figure 3 of CROSSMAN, reproduced below.



The teachings of HIGGINS fail to compensate for the deficiencies of CROSSMAN.

One of ordinary skill and creativity would thus not produce claims 15 and 16 of the present invention from a knowledge of the teachings of CROSSMAN and HIGGINS. A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

CONCLUSION

The rejections have been overcome, obviated or rendered moot, and it is believed that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

Docket No. 3003-1159
Appln. No. 10/518,513

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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